

g

GE Medical Systems, LLC (GE Healthcare)

3000 N. Grandview Blvd. W-1140  
Waukesha, WI 53188**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

**Date:** June 7, 2012

**Submitter:** GE Medical Systems, LLC (GE Healthcare)  
3000 N. Grandview Blvd., W-1140  
Waukesha, WI 53188

**Primary Contact:** John Jaeckle  
Chief Regulatory Affairs Strategist  
GE Medical Systems, LLC  
Tel: 262-424-9547  
e-mail: [john.jaeckle@ge.com](mailto:john.jaeckle@ge.com)

**Secondary Contact:** Helen Peng  
Regulatory Affairs Leader, RAC  
GE Medical Systems, LLC  
Tel: 262-548-5091  
e-mail: [hong.peng@med.ge.com](mailto:hong.peng@med.ge.com)

**PRODUCT IDENTIFICATION**

**Device Trade Name:** Discovery CT750 HD

**Common/Usual Name:** Computed Tomography X-ray System

**Classification Name:** Computed Tomography X-ray System per  
21CFR892.1750

**Product Code:** 90-JAK

**Manufacturer**  
**/ Design Location:** GE Medical Systems, LLC (GE Healthcare)  
3000 N. Grandview Blvd.  
Waukesha, WI 53188

**Manufacturing Location(s):** GE Medical Systems, LLC (GE Healthcare)  
3000 N. Grandview Blvd.  
Waukesha, WI 53188

**Distributor:** GE Medical Systems, LLC (GE Healthcare)  
3000 N. Grandview Blvd.



Waukesha, WI 53188

**Marketed Devices:**

The Discovery CT750 HD with GSI Cardiac Option is of comparable type and substantially equivalent to GE Medical Systems' currently marketed Computed Tomography X-ray Systems that comply with the same standards. In addition, the system has similar intended use as other GE Computed Tomography X-ray Systems and the same intended use as the unmodified device. However the modified device's indications for use have been revised to match the system capabilities as substantiated in the engineering and clinical testing provided. The system is labeled as the Discovery CT750 HD.

**Predicate (unmodified) Device(s):**

K081105 – Discovery CT750 HD

**DEVICE DESCRIPTION**

The Discovery CT750 HD CT Scanner System with GSI Cardiac Option is composed of a gantry, patient table, operator console, computer, and PDU and includes image acquisition hardware, image acquisition and reconstruction software, associated accessories and connections/interfaces to accessories.

The Discovery CT750 HD CT Scanner System with GSI Cardiac Option is intended to be a head and whole body CT system incorporating the same basic fundamental operating principles and the same indications for use as the predicate device. Materials and construction are equivalent to our existing marketed products, which are compliant with UL 60601-1, IEC 60601-1 and associated collateral and particular standards, 21CFR Subchapter J, and NEMA XR-25. It has been developed under the same GE quality system and has successfully completed all design controls, including risk management, verification, and validation.

**Indications for Use:**

The Computed Tomography X-ray system is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), Cardiac, Spectral, and Gated acquisitions for all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results.

The system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications for both single kV acquisitions and with the fast kV switching spectral imaging option (GSI).



The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

If the spectral imaging option is included on the system, the system can acquire CT images using different kV levels of the same anatomical region of a patient in a single rotation from a single source. The differences in the energy dependence of the attenuation coefficient of the different materials provide information about the chemical composition of body materials. This approach enables images to be generated at energies selected from the available spectrum to visualize and analyze information about anatomical and pathological structures.

GSI provides information of the chemical composition of renal calculi by calculation and graphical display of the spectrum of effective atomic number. GSI Kidney stone characterization provides additional information to aid in the characterization of uric acid versus non-uric acid stones. It is intended to be used as an adjunct to current standard methods for evaluating stone etiology and composition.

#### **Technology:**

The Discovery CT750 HD with GSI Cardiac Option employs the same fundamental scientific technology as the unmodified device.

#### **Adverse Effects on Health:**

Potential electrical, mechanical, and radiation hazards are identified in risk management including hazard analysis and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence and certification to industry and international standards. (UL/CSA and IEC60601-1 Ed.3 and associated collateral and particular standards for CT).
- Compliance to applicable CDRH 21CFR subchapter J requirements.
- Compliance to NEMA XR-25

The device is designed and manufactured under the Quality System Regulations of 21CFR 820.

#### **Determination of Substantial Equivalence:**

The Discovery CT750 HD with GSI Cardiac Option has completed testing and is in compliance with IEC 60601-1 Ed. 3 and its associated collateral and particular standards, 21CFR Subchapter J, and NEMA XR-25. The device has successfully completed all testing per our quality system as well as comparison testing to the unmodified device. It was designed and is manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Required Reviews
- Design Reviews
- Testing on unit level (Module verification)

- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

### **Summary of Additional Testing**

In addition to the verification and validation testing successfully completed as required by GE Healthcare's quality system, additional engineering and clinical performance testing was performed to provide the requisite data to substantiate performance claims, revised indications, safety and efficacy, and ultimately substantial equivalence.

#### **Engineering Testing**

The bench testing used two custom designed phantoms to simulate the cardiac imaging tasks. The test scan techniques used were selected to align with clinically used protocols for cardiac scanning. Statistical analysis of the results demonstrated the significance of the findings.

For coronary plaque modeling the material hydroxyapatite (HAP) was selected because of publications demonstrating that it closely matches the composition of calcified plaques in coronary arteries. To evaluate coronary lumen and plaque visualization, dilute Iodine-filled vessels contained in an in-house custom phantom with HAP inserts was used to demonstrate the enhanced assessment capabilities when using GSI cardiac including its material separation capability.

Additionally, three actual clinical cases with an Iodine and Calcium MD images and wide range of monochromatic images were shown for comparison.

Testing was also performed to demonstrate the ability for the GSI acquisition to reduce beam hardening artifact in a simulated cardiac environment, and thereby improve CT number accuracy which is important for accurate perfusion calculations. For this test another custom cardiac phantom was utilized. This polyurethane phantom was designed to mimic two heart chambers, an aorta, and a small "myocardial ischemic" defect. The chambers and aorta were filled with water and/or varying concentrations of iodine.

#### **Clinical Testing**

Sample clinical images were obtained from 29 subjects at 3 sites using the GSI cardiac option under IRB and informed consent. Two radiologists at each site independently assessed, using a Likert scale, the diagnostic quality of the images and additional information from the output of the GSI cardiac feature (monochromatic + material density images).

The patient population consisted of any patient with known or suspected abnormality involving the heart scheduled for a physician ordered CT exam or who recently had a routine CT scan or cardiac cath procedure within the past 30 days. This patient data was representative of a wide range of heart rates and patient sizes.

The results demonstrated that the output of the GSI cardiac feature (monochromatic + material density images) provide diagnostic images and include additional information related to material composition obtained as a result of GSI scanning.

Additionally, data from an independent clinical study using GSI to characterize urinary tract stones in a simulated abdominal phantom and with in-vivo patient scans, was submitted.

Twenty stones of pure crystalline composition [Uric acid (UA), struvite, cystine, and calcium oxalate monohydrate (COM)] were assessed in a phantom as well as 11 patients with urinary tract stones were evaluated. UA and non-UA stones were defined using a two-material decomposition (MD-Iodine/Water) algorithm. The stone HU was also studied to determine its performance in predicting the composition. Ex-vivo analysis of the stone using polarized microscopy with infrared spectrophotometry served as the gold standard.

Of the 59 verified stones (phantom=20 and patients=39, mean size- 6 mm) there were 16 UA and 43 non-UA type. The material density (MD) images were 100% sensitive and accurate in characterizing UA versus non-UA stones. In patients, Effective Z identified 83% of calcium stones (n=24) and in stones of mixed type it accurately identified the dominant composition. The HU measurements alone were 71% sensitive and 69% accurate in characterizing the UA stones. The results demonstrate that GSI can provide accurate adjunct information that may predict UA and from non-UA stone composition in-vitro and in-vivo.

**Substantial Equivalence Conclusion:**

Based on the conformance to standards, development under our quality system, and the engineering and clinical testing provided, GE Medical Systems believes that the Discovery CT750 HD with GSI Cardiac Option is as safe and effective, and performs in a substantially equivalent manner to the predicate device Discovery CT750 HD (K081105).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room – WO66-G609  
Silver Spring, MD 20993-0002

JUN 12 2012

Mr. John Jaeckle  
Chief Regulatory Affairs Strategist  
GE Medical Systems, LLC  
3000 N. Grandview Blvd., W - 1140  
WAUKESHA WI 53188

Re: K120833  
Trade/Device Name: Discovery CT750 HD  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography x-ray system  
Regulatory Class: II  
Product Code: JAK  
Dated: March 16, 2012  
Received: March 19, 2012

Dear Mr. Jaeckle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

---

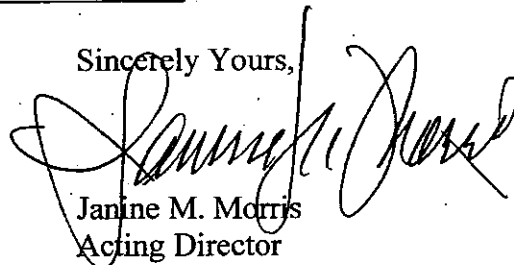
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris  
Acting Director  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

---

## Indications for Use

**510(k) Number (if known):** K120833

**Device Name:** Discovery CT750 HD

### Indications for Use:

The Computed Tomography X-ray system is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), Cardiac, Spectral, and Gated acquisitions for all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results.

The system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications for both single kV acquisitions and with the fast kV switching spectral imaging option (GSI).

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

If the spectral imaging option is included on the system, the system can acquire CT images using different kV levels of the same anatomical region of a patient in a single rotation from a single source. The differences in the energy dependence of the attenuation coefficient of the different materials provide information about the chemical composition of body materials. This approach enables images to be generated at energies selected from the available spectrum to visualize and analyze information about anatomical and pathological structures.

GSI provides information of the chemical composition of renal calculi by calculation and graphical display of the spectrum of effective atomic number. GSI Kidney stone characterization provides additional information to aid in the characterization of uric acid versus non-uric acid stones. It is intended to be used as an adjunct to current standard methods for evaluating stone etiology and composition.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K120833